### HEARTMATE 3TH LVAD WITH FULL MAGLEV TH FLOW TECHNOLOGY

# THEIR FUTURE STARTS WITH YOU



HEARTMATE 3<sup>™</sup> LVAD with Full MagLev<sup>™</sup> Flow Technology



# HEARTMATE 3<sup>™</sup> LVAD DELIVERS **UNPRECEDENTED<sup>\*</sup> SURVIVAL AND** SAFETY OUTCOMES\*\*1

In the MOMENTUM 3 trial, the largest LVAD trial ever conducted,\*\*\* the HeartMate 3 LVAD demonstrated at 2 years:



The highest published 2-year survival rate and the lowest published stroke and thrombosis rates for continuous-flow LVADs<sup>1-5</sup>

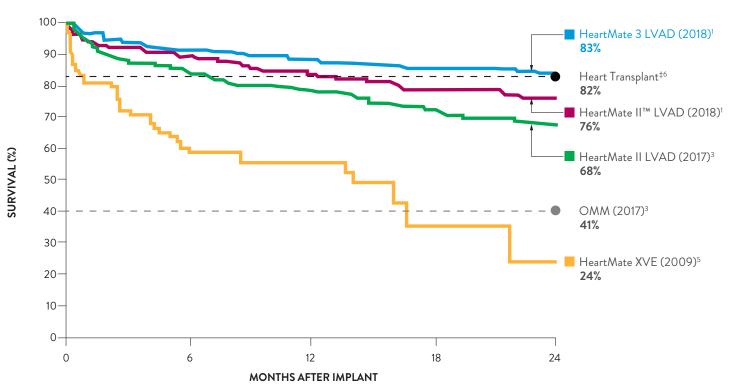
HeartMate 3 LVAD outcomes made possible by Full MagLev<sup>™</sup> Flow Technology.

### **NOW APPROVED FOR DESTINATION THERAPY**

The HeartMate 3 Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure.

# LANDMARK SURVIVAL WITH HEARTMATE 3<sup>™</sup> LVAD

### NOW COMPARABLE TO TRANSPLANT SURVIVAL AT 2 YEARS<sup>‡6</sup>



OMM = Optimal Medical Management.

Based on published data from multicenter experience and separate studies, which may involve different patient populations and other variables. Not a head-to-head comparison. Data presented for informational purposes only. Please refer to the HeartMate II and HeartMate 3 LVAD Instructions for Use about indications, contraindications, adverse events, warnings, and precautions.

### UNPRECEDENTED SURVIVAL AT 2 YEARS<sup>1</sup>



#### SUPERIOR EVENT-FREE SURVIVAL AT 2 YEARS (PRIMARY ENDPOINT) +++1



# **EXCELLENT SAFETY PROFILE**

### LOWEST PUBLISHED STROKE AND THROMBOSIS RATES FOR CONTINUOUS-FLOW LVADs<sup>1-5</sup>

	MOMENTUM 3 2018 <sup>1</sup>		ENDURANCE 2017 <sup>2</sup>	
<b>10%</b> STROKE <sup>1</sup>	HeartMate 3™ LVAD (n = 189)	HeartMate II™ LVAD (n = 172)	HVAD <sup>§</sup> LVAD (n = 296)	HeartMate II LVAD (n = 149)
	<b>10.1% / 0.08</b> Stroke (% / EPPY)	19.2% / 0.18 Stroke (% / EPPY)	29.7% / 0.29 Stroke (% / EPPY)	12.1% / 0.09 Stroke (% / EPPY)

HeartMate 3 LVAD stroke rates decreased after 6 months, with a 0.04 EPPY from 6 months through 2-year follow-up. EPPY = Events Per Patient Year.

#### **ENDURANCE 2017<sup>2</sup> MOMENTUM 3 2018<sup>1</sup>** % **HVAD**§ HeartMate 3 HeartMate II HeartMate II LVAD LVAD LVAD LVAD (n = 190) (n = 176) (n = 149) (n = 295) **THROMBOSIS**<sup>+1</sup> 1.1% 10.7% 15.7% 6.4% Pump Thrombosis (%) Pump Thrombosis (%) Pump Thrombosis (%) Pump Thrombosis (%)

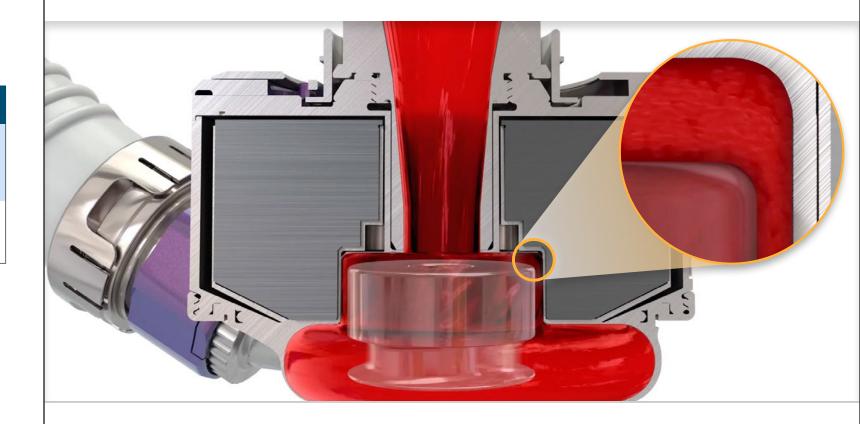
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#### HEARTMATE 3 LVAD GASTROINTESTINAL BLEEDING (27%) IS SIMILAR TO OTHER LVADs, WHILE MAINTAINING MINIMAL PUMP THROMBOSIS.<sup>3</sup>

# **OUTCOMES MADE POSSIBLE BY FULL MAGLEV<sup>™</sup> FLOW TECHNOLOGY**

Full MagLev Flow Technology maintains gentle blood handling to minimize complications and reduce hemocompatibility-related adverse events.

- Fully levitated, self-centering rotor that does not require hydrodymamic or mechanical bearings
- Large, consistent blood flow pathways to reduce shear stress<sup>7</sup>
- Intrinsic pulsatility to reduce blood stasis and minimize thrombus<sup>7,8</sup>



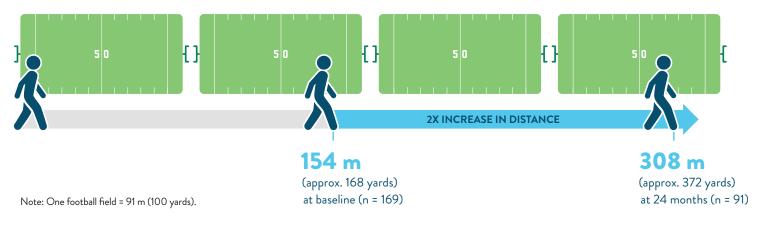
# MAKING A MEANINGFUL DIFFERENCE IN PATIENTS' LIVES

### SIGNIFICANT IMPROVEMENT IN NEW YORK HEART ASSOCIATION (NYHA) FUNCTIONAL CLASS<sup>1</sup>



78% of patients improved from NYHA Class IIIB/IV at baseline to NYHA Class I/II by 6 months, with sustained improvement of 79% of patients through 2 years (*P*<0.0001).<sup>1</sup>

### SIGNIFICANT INCREASE IN 6-MINUTE WALK DISTANCE



#### IMPROVED QUALITY OF LIFE<sup>1</sup>

**28 POINT IMPROVEMENT** in KCCQ overall summary score at 3 months was sustained out to 2 years (*P*<0.0001).

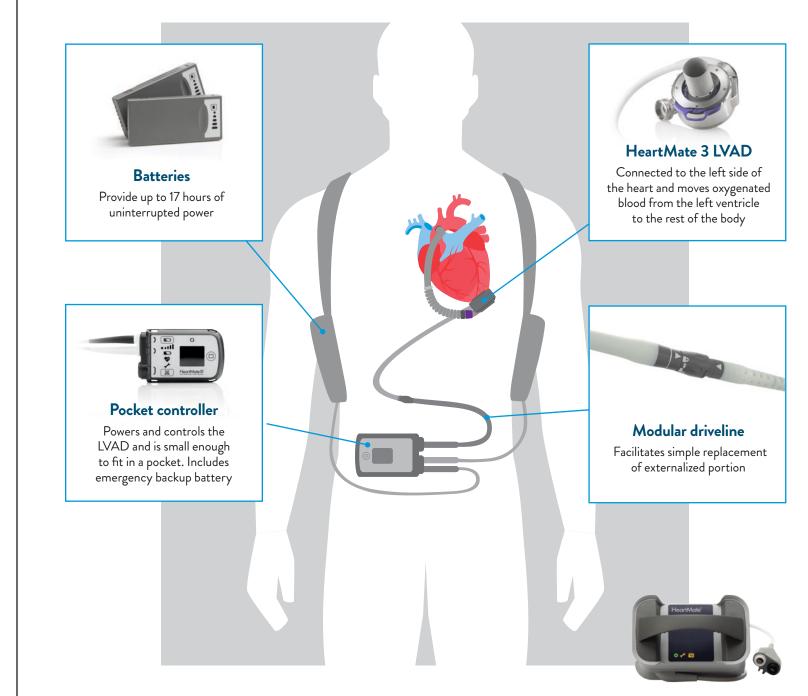
KCCQ = Kansas City Cardiomyopathy Questionnaire.

### **REDUCTION IN REHOSPITALIZATIONS**<sup>°</sup>

- 8.3 FEWER hospital days
- **51% REDUCTION** in average cumulative cost per patient-year

# HEARTMATE 3<sup>™</sup> LVAD SYSTEM

### A better experience for clinicians and patients



### Mobile Power Unit (MPU)

Plug-in power source

### THEIR FUTURE STARTS WITH YOU

Choosing HeartMate 3<sup>™</sup> LVAD, you can go above and beyond to make a meaningful difference in your patients' lives.

### EMPOWERING THE TRANSFORMATION OF HEART FAILURE

### BEAT AS ONE<sup>™</sup>

\*Based on Heart Mate LVAD highest published survival and lowest published stroke and thrombosis rates in continuous-flow LVAD category of devices in the U.S.<sup>1-5</sup> \*\*HeartMate 3™ LVAD demonstrated superiority in event-free survival (primary endpoint) in the MOMENTUM 3 trial compared to HeartMate II™ LVAD.

- \*\*\*Ongoing evaluation of more than 2000 patients on short- and long-term therapy of devices in the U.S.<sup>1,</sup>
- +Suspected pump thrombosis events occurred in 2 patients with the centrifugal-flow pump, but neither were confirmed. \$82% 2-year survival for heart transplant patients between 2009 and 2015.2

++++Survival at 2 years free of disabling stroke or reoperation to replace or remove a malfunctioning device.1

References: 1. Mehra MR, Goldstein DJ, Uriel N, et al, for the MOMENTUM 3 Investigators. Two-year outcomes with a magnetically levitated cardiac pump in heart failure. N Engl J Med. 2018;378:1386-1395. 2. Rogers JG, Pagani F, Tatooles A, et al. Intrapericardial left ventricular assist device for advanced heart failure. New Engl J Med. 2017;376:451-460. 3. Starling RC, Estep JD, Horstmanshof DA, et al; ROADMAP Study Investigators. Risk assessment and comparative effectiveness of left ventricular assist device and medical management in ambulatory heart failure patients: the ROADMAP Study 2-year results. JACC Heart Fail. 2017 Mar 30. 4. Jorde UP, Kushwaha SS, Tatooles AJ, et al. Results of the destination therapy post-food and drug administration approval study with a continuous flow left ventricular assist device: a prospective study using the INTERMACS registry (Interagency Registry for Mechanically Assisted Circulatory Support). J Am Coll Cardiol. 2014;63:1751-1757. 5. Slaughter MS, Rogers JG, Milano CA, et al. Advanced heart failure treated with continuous-flow left ventricular assist device. N Engl J Med. 2009;361:2241-2251. 6. Lund LF, Khush KK, Cherikh WS, et al. The Registry of the International Society for Heart and Lung Transplantation: Thirty-fourth Adult Heart Transplantation Report-2017; Focus theme: allograft ischemic time. J Heart Lung Transplant. 2017;36:1037-1046. 7. Bourque K, Cotter C, Dague C, et al. Design rationale and preclinical evaluation of the HeartMate 3 Left Ventricular Assist System for hemocompatibility. Am Soc Artificial Int Organs. 2016;62:375-383 8. Bourque K, Dague C, Farrar D, et al. In vivo assessment of a rotary left ventricular assist device-induced artificial pulse in the proximal and distal aorta. Artificial Organs. 2006;30:638-642. 9. Mehra MR, Salerno C, Cleveland JC, et al. Health care resource use and cost implications in the MOMENTUM 3 long-term outcome study: a randomized controlled trial of a magnetically levitated cardiac pump in advanced heart failure. Circulation. 2018 May 27. pii: CIRCULATIONAHA.118.035722. doi: 10.1161/CIRCULATIONAHA.118.035722. [Epub ahead of print].

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#### Rx Only

#### **Important Safety Information**

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The Heart Mate 3 Left Ventricular Assist System is indicated for providing short-and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure.

Contraindications: The HeartMate 3 Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy. Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) or device thrombosis.



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